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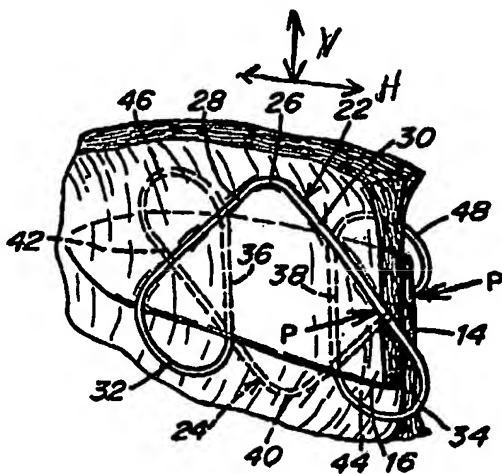
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(54) Title: PATENT FORAMEN OVALE (PFO) CLOSURE CLIPS



(57) Abstract: The present invention provides a patent foramen ovale (PFO) closure clip. The clips of the present invention include two closure members joined by at least two spaced central connecting members. Each of the at least two spaced central connecting members is attached to each closure member at a location on a periphery of the closure member. The clips are designed such that the at least two central connecting members extend through the inclined PFO tunnel and the two closure members compress the overlapping layers of septal tissue, i.e. septum primum and septum secundum, together to close the PFO tunnel. The clips of the present invention may be formed of various materials. In at least some embodiments, the clips are formed of metals, nonmetallic materials, bioabsorbable polymers, spring steel, shape memory materials, bioabsorbable shape memory polymers, or combinations thereof. The clips of the present invention take various forms depending, in part, upon the distribution of force required to close a given PFO. Thus, in some embodiments, the closure members include arcuate peaks. In other embodiments, the closure members include loops. In

still other embodiments, the closure members include prongs. In yet other embodiments, the closure members include centering elements for centering the device in the desired delivery location. In at least some embodiments, the clips of the present invention are repositionable and/or retrievable. In some embodiments, at least one of the closure members includes a tissue scaffold.

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PATENT FORAMEN OVALE (PFO) CLOSURE CLIPS

Field of the Invention

[0001] The present invention relates to devices and methods that are used to close septal openings. In particular, this invention is directed to devices and methods that are used to close a patent foramen ovale (PFO) in the septum between the left atrium and right atrium.

Background of the Invention

[0002] A PFO, illustrated in Figure 1, is a persistent, one-way, usually flap-like opening in the wall between the right atrium 10 and left atrium 12 of the heart. Because left atrial (LA) pressure is normally higher than right atrial (RA) pressure, the flap usually stays closed. Under certain conditions, however, right atrial pressure can exceed left atrial pressure, which creates the possibility that blood could pass from the right atrium to the left atrium and allow blood clots to enter the systemic circulation. It is desirable that this circumstance be eliminated.

[0003] The foramen ovale serves a desired purpose when a fetus is gestating in utero. Since blood is oxygenated through the umbilical chord, and not through the developing lungs, the circulatory system of a heart in a fetus allows the blood to flow through the foramen ovale as a physiologic conduit for right-to-left shunting. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure results in functional closure of the foramen ovale. This functional closure is subsequently followed by anatomical closure of the two over-lapping layers of tissue: septum primum 14 and septum secundum 16. However, a PFO has been shown to persist in a number of adults.

[0004] The presence of a PFO is generally considered to have no therapeutic consequence in otherwise healthy adults. Paradoxical embolism via a PFO is considered in the diagnosis for patients who have suffered a stroke or transient ischemic attack (TIA) in the presence of a PFO and without another cause of ischemic stroke. While there is currently no definitive proof for a cause-effect relationship, many studies have confirmed a strong association between the presence of a PFO and the risk for paradoxical embolism or stroke. In addition, there is significant evidence that patients with PFO who have had a cerebral vascular event are at increased risk for future, recurrent cerebrovascular events.

[0005] Accordingly, patients with an increased future risk are considered for prophylactic medical therapy to reduce the risk of a recurrent embolic event. These patients are commonly treated with oral anticoagulants, which have the potential for adverse side effects, such as hemorrhaging, hematoma, and interactions with a variety of other drugs. The use of these drugs can alter a person's recovery and necessitate adjustments in a person's daily living pattern.

[0006] In certain cases, such as when anticoagulation is contraindicated, surgery may be necessary or desirable to close the PFO. The surgery would typically include suturing a PFO closed by attaching septum secundum to septum primum. This sutured attachment can be accomplished with either an interrupted or a continuous stitch and is a common way a surgeon shuts a PFO under direct visualization.

[0007] Umbrella devices and a variety of other similar mechanical closure designs, developed initially for percutaneous closure of atrial septal defects (ASDs), have been used in some instances to close PFOs. These devices have the potential to allow patients to avoid the potential side effects often associated with anticoagulation therapies and the risks of invasive surgery. However, umbrella devices and the like that are designed for ASDs are not optimally suited for use as a PFO closure device.

[0008] Currently available designs of septal closure devices present drawbacks, including that the implantation procedure is technically complex. Additionally, there are not insignificant complications due to thrombus, fractures of the components, conduction system disturbances, perforations of heart tissue, and residual leaks. Many devices have high septal profile and may include large masses of foreign material, which may lead to unfavorable body adaptation of a device. Since ASD devices are designed to occlude a hole, many lack anatomic conformability to the PFO flap-like anatomy. That is, when inserting an ASD device to close a PFO, the narrow opening and the thin flap may form impediments to proper deployment. Even if an occlusive seal is formed, the device may be deployed in the heart on an angle, which could leave some components not securely seated against the septum. Finally, some septal closure devices are complex to manufacture, which may result in lack of consistency in product performance.

[0009] The present invention is designed to address these and other deficiencies of the prior art septal closure devices.

Summary of the invention

[0010] The present invention provides patent foramen ovale (PFO) closure clips. The clips of the present invention include two closure members joined by at least two spaced central connecting members. Each of the at least two spaced central connecting members is attached to each closure member at a location on the periphery of the closure member. The clips are designed such that the at least two central connecting members extend through the inclined PFO tunnel and the two closure members compress the overlapping layers of septal tissue, *i.e.* septum primum and septum secundum, together to close the PFO tunnel.

[0011] The clips of the present invention may be formed of various materials. In at least some embodiments, the clips are formed of metals, nonmetallic materials, bioabsorbable polymers, spring steel, shape memory materials, bioabsorbable shape memory polymers, or combinations thereof.

[0012] The clips of the present invention take various forms depending, in part, upon the distribution of force required to close a given PFO. Thus, in some embodiments, the closure members include arcuate peaks. In other embodiments, the closure members include loops. In still other embodiments, the closure members include prongs. In yet other embodiments, the closure members include centering elements.

[0013] In at least some embodiments, the clips of the present invention are repositionable and/or retrievable. In some embodiments, at least one of the closure members includes a tissue scaffold.

Brief Description of the Drawings

[0014] Figure 1 is a diagrammatic sectional view of a Patent Foramen Ovale (PFO) between the right atrium and the left atrium;

[0015] Figures 2a and 2b are a front elevational view and a side view, respectively, of a PFO closure clip according to a first embodiment of the present invention;

[0016] Figures 3a and 3b are side elevational views of the PFO closure clip of Figure 2; Figure 3b illustrates a device disposed in a PFO;

[0017] Figure 4 is a front elevational view of the PFO closure clip of Figure 2 in place in a PFO as seen from the right atrium;

[0018] Figures 5a and 5b are front elevational views of a PFO closure clip according to a second embodiment of the present invention as seen from the left and right atria, respectively;

[0019] Figures 6a and 6b are front elevational views of a PFO closure clip according to a third embodiment of the present invention as seen from the left and right atria, respectively;

[0020] Figures 7a and 7b are front elevational views of a PFO closure clip according to a fourth embodiment of the present invention as seen from the left and right atria, respectively;

[0021] Figures 8a and 8b are front elevational views of a PFO closure clip according to a fifth embodiment of the present invention as seen from the left and right atria, respectively;

[0022] Figure 9 is a perspective view of a PFO closure clip according to a sixth embodiment of the present invention;

[0023] Figure 10 is a front elevational view of the PFO closure clip of Figure 9;

[0024] Figure 11 is a side elevational view of the PFO closure clip of Figure 9 disposed in a PFO;

[0025] Figure 12 is a perspective view of the PFO closure clip of Figure 9 disposed in a PFO as seen from the right atrium;

[0026] Figure 13 is a front elevational view of a PFO closure clip according to a seventh embodiment of the present invention;

[0027] Figure 14 is a side elevational view of the PFO closure clip of Figure 13 straightened for insertion into a sheath;

[0028] Figure 15 is a side elevational view of the PFO closure clip of Figure 13 in place in a PFO;

[0029] Figure 16 is a front elevational view of an eighth embodiment of a PFO closure clip according to the present invention; and

[0030] Figure 17 is a front elevational view of a ninth embodiment of a PFO closure clip according to the present invention.

Description of the Preferred Embodiments

[0031] The clip devices of the present invention are intended to clip septum primum to septum secundum to thereby minimize the flow of blood between the right and left atria. The clip devices assist in reducing the risk of stroke by preventing the passage of embolic particles from the right atrium to the left atrium through a PFO. To accomplish this, the clip devices apply a compressive force to the overlapping layers of septal tissue between the right and left atria, *i.e.* septum primum and septum secundum. In at least some embodiments, the applied compressive force “pulls” the more flexible septum primum toward septum secundum, thereby closing the PFO without significantly distorting the septum, as occurs with many of the septal closure devices of the prior art. In this application, compressive force is intended to include force sufficient to bring septum primum and septum secundum together to provide a closing effect. In some embodiments, the clip provides mechanical closure at enough points of contact along the PFO that the single largest remaining conduit is reduced to a size deemed small enough to block stroke-inducing embolic particles from crossing through the PFO tunnel. In other embodiments, the clip provides substantially complete closure along the entire PFO length. Because the clip devices of the present invention do not distort the defect, the overlapping layers of septal tissues may themselves be used to close the defect as they are compressed by the clip device. Accordingly, in at least some embodiments, the application of a compressive force to the septal tissues using the clip devices of the present invention may ultimately induce anatomical closure of septum primum and septum secundum (*i.e.* septum primum and septum secundum will fuse together by natural processes).

[0032] The clip devices of the present invention may be formed of metal wire, nonmetallic materials, bioabsorbable polymers, spring steel, shape memory materials (*e.g.* nitinol), bioabsorbable shape memory polymers, or combinations of the foregoing materials. In some embodiments, the clip devices are formed of a single piece of material, while in other embodiments, the clip devices are formed of multiple pieces of material.

[0033] In particular embodiments, the clip devices are formed of shape memory material (*e.g.* nitinol), which allows the clips to resume and maintain their intended shape

following deployment *in vivo*. A clip according to the present invention may use the thermal shape memory properties of a shape memory material, the superelastic properties of a shape memory material, or some combination of the two. In other particular embodiments, the clip devices are cut into their desired shapes from sheets of material, including bioabsorbable shape memory polymers. Those skilled in the art will recognize that the device could be made of a combination of materials. Those of skill in the art will be able to identify biocompatible clip materials suited for particular applications, and the manufacturing techniques that would be used to configure the material into specific clip designs.

[0034] In at least some embodiments, the clip devices of the present invention include first and second closure members connected by at least two spaced central connecting members. Each central connecting member is attached to each closure member at a point on the periphery of the closure member. The central connecting member may be any strand of material, *e.g.* a wire or portion of wire, that connects the closure members. The connecting members are intended to pass through the PFO tunnel. After deployment into the heart, the second closure member is located in the left atrium and the first closure member is located in the right atrium, such that the central connecting members extend through the PFO tunnel, as described below for the various embodiments of the present invention.

[0035] The first and second closure members may be constituted of a material or be configured to apply a compressive force to the overlapping layers of septal tissue. Further, the movement of the at least two spaced central connecting members extending through the PFO tunnel may be limited by the edges of the PFO tunnel (which is usually between 1 mm and 20 mm wide), thereby ensuring the clip device remains horizontally centered across the defect and consistently applies compressive force to the septal tissues at the locations necessary to effect closure of the defect. This accurate and consistent application of localized force permits the use of a smaller closure device.

[0036] In some embodiments, the clip devices of the present invention include only one closure member and at least one connecting member. The connecting member passes through the PFO tunnel and secures the closure member in place.

[0037] The closure members of the clip devices may take various forms depending, in part, upon the distribution of force desired to effect closure of a given defect. In this

application, the term defect is applied to any anatomical configuration requiring treatment. In particular, the defect can be a PFO which may allow, or allows, blood to flow from the right atrium to the left atrium. The shape of each closure member determines the location(s) at which the compressive force is applied to the overlapping layers of septal tissue.

[0038] In some embodiments, the compressive force is concentrated at the center of the longitudinal distance of the PFO tunnel. In other embodiments, the compressive force is distributed along the length of the defect. In still other embodiments, the compressive force is applied toward the edges of the PFO defect. Of course, the force may be a combination of the above-described forces. In at least some embodiments, the closure devices of the present invention are low profile devices, *i.e.* the closure members contact the septal tissue both inferior to and superior to the PFO tunnel entrance in the left atrium or the right atrium or both. The device may include configurations that are centered horizontally or vertically in the PFO. These and other embodiments of the clip devices of the present invention are described below. In the Figures, the directional indications, *e.g.* downward and upward, are meant to facilitate understanding of the invention and are not intended to limit the invention in any manner.

[0039] Referring to Figures 2-4, a first embodiment of the PFO closure clip of the present invention, indicated generally at 18, is designed to extend through the inclined PFO tunnel 20 between septum secundum 16 and septum primum 14 to engage the outer surfaces of septum secundum 16 and septum primum 14 in both the left and right atria. As shown in Figure 3b, the compressive force applied by the closure clip 18 forces the layers of septal tissue together to close the PFO tunnel 20, thereby inducing anatomical closure of septum primum and septum secundum.

[0040] The clip 18 includes a first closure member 22 that overlies a second closure member 24. The first and second closure members 22 and 24 of the clip 18 are biased toward one another and, as shown in Figure 2, are connected at their peripheries by connecting strands 36 and 38. The connecting strands are relatively straight and are configured to pass through the PFO tunnel. In other embodiments, there may be a slight curve to the connecting strands. The first closure member includes an arcuate peak 26 that joins two elongate side strands 28 and 30, both of which are oriented away from the peak 26 to form, as illustrated, a triangle. The angle of the peak 26 is broad enough to allow the strands 28 and 30 to extend over a sufficient amount of the PFO but not so

much as to interfere with the function of the heart. Of course, the peak 26 may be designed with a large angle, *e.g.* greater than 90° and the side strands 28 and 30 may be rounded to cover the PFO closure. As described below, smaller angles are also contemplated according to this invention. At their lowermost extremities side strands 28 and 30 are looped to provide spaced bottom loops 32 and 34 at a radius sufficient to direct the wires into the PFO tunnel for the first closure member. Loops 32 and 34 extend into straight, spaced, elongate connecting strands 36 and 38, respectively, which connect the first closure member 22 to the second closure member 24. As previously indicated, the straight, spaced, elongate connecting strands 36 and 38 are designed to extend through the inclined PFO tunnel 20 between septum primum and septum secundum.

[0041] The second closure member 24 is substantially identical in construction to the first closure member 22 but is oriented in a reverse manner to the first closure member 22.

The second closure member includes an arcuate peak 40, aligned with but spaced opposite to the arcuate peak 26, that joins two outwardly angled, elongate side strands 42 and 44. At their uppermost extremities, elongate side strands 42 and 44 are looped to provide spaced top loops 46 and 48, respectively, for the second closure member 24, which are substantially aligned with but spaced opposite to bottom loops 32 and 34. Loops 46 and 48 extend into straight, spaced, elongate, connecting strands 36 and 38, respectively. The same configuration adjustments may be made to the second closure member as suggested for the first closure member.

[0042] Figures 3a, 3b, and 4 show the clip 18 in place to close a PFO. Clip 18 may be elongated and deployed through a catheter. The catheter enters the right atrium and is inserted through the PFO tunnel into the left atrium. Closure member 24 is then ejected into the left atrium, where it resumes the shape shown in Figure 4. The catheter is then withdrawn through the PFO tunnel into the right atrium such that spaced, elongate connecting strands 36 and 38 are deployed and extend through the PFO tunnel. Finally, closure member 22 is deployed into the right atrium, where it resumes the shape shown in Figure 4. When so deployed, closure members 22 and 24 apply a compressive force, indicated by the arrows P, to the septal tissues, as discussed above. The vertical direction is indicated by arrows V, and the horizontal direction is indicated by arrows H.

[0043] Once deployed, clip 18 is centered horizontally across the PFO because the movement of spaced, elongate connecting strands 36 and 38 is limited by the edges of the PFO tunnel. Thus, clip 18 consistently applies pressure to the overlapping layers of septal

tissue at the locations where outwardly angled side strands **28** and **42** and **30** and **44** overlap. Lesser pressures are also applied at the locations where peaks **26** and **40** and loops **32**, **34**, **46**, and **48** engage septum primum and septum secundum.

[0044] As illustrated, the angle of peak **26**, *i.e.* the angle formed by wires **28** and **30**, is slightly larger than 90 degrees. Of course, one skilled in the art will recognize that the “peak angle” could be 180°, which would effectively create a transverse strand across the tissues forming the PFO tunnel. The “peak angles” could be different on one side of the septum than on the other, *e.g.* the “peak angles” could vary on the closure members in the left and right atria. When determining the “peak angles” for a given clip according to the invention, one design consideration would be the difference in thickness between septum secundum and septum primum. The device should have a design that compresses (or at least holds) septum primum and septum secundum together.

[0045] Depending on the anatomy of the septum and the forces applied by the clip, the loops and peaks may contact the septum. Since the septum is generally stiff but not actually rigid, the tissue will generally conform to the forces applied to it. This is particularly true for septum primum. Accordingly, any illustration of the clip as shown schematically in the heart should be considered as exemplary and not limiting.

[0046] In at least some embodiments, the closure clip of the present invention is repositionable and/or retrievable. For example, as shown in Figure 5, an attachment point **27** may be included on peak **26a** of closure member **22a** to facilitate manipulation of the clip device during and following its deployment. In the various embodiments described below, reference numerals which apply to a feature of the clip are used consistently and are given a letter identifier. For example, peak **26** is peak **26a** in the embodiment described with reference to Figure 5, **26b** in the embodiment described with reference to Figure 6, etc. In particular embodiments, the closure clip may be modified such that peak **26a** and, correspondingly, point **27** are pointing downwards, as shown in Figures 6a, 6b, 7a, 7b, 8a, 8b and described below, so as to further facilitate manipulation and recovery of the clip device.

[0047] The closure clip of the present invention may have a variety of configurations. In one embodiment (Figures 6a and 6b), the clip is modified to concentrate the compressive force along the center of the PFO. As shown in Figure 6a, loops **46b** and **48b** of second closure member **24b** are folded inward such that strands **42b** and **44b** are straightened and

elongated through the vertical center of closure member **24b**, terminating in arcuate peak **40b**. Additionally, as shown in Figure 6b, spaced loops **21b** and **23b** may be formed opposite loops **32b** and **34b** in the uppermost extremities of strands **28b** and **30b** of first closure member **22b**, such that peak **26b** is forced downwards and elongated through the vertical center of closure member **22b**. The elongated central peak **40b** of closure member **24b** and the elongated peak **26b** of closure member **22b** concentrate the compressive force at the center of the defect in the left and right atria, respectively. Applying pressure to the center of the defect, rather than its ends, is considered to produce a more effective closure. Further, as noted above, the downwardly-pointing peak **26b** of closure member **22b** in the right atrium facilitates manipulation and recovery of the clip following its deployment.

[0048] The clip **18c** may also be modified to ensure it remains vertically centered after being deployed across the PFO (Figures 7a and 7b). "Vertically centered" refers to the portion of the device along the length of the PFO. It may be important to ensure that the device maintains a position along the length (longitudinal) of the PFO. In order to accomplish this using the structure of the device (instead of or in addition to a compressive force applied by the clip), the strands may be configured to limit the longitudinal motion of the device. In particular, as shown in Figure 7a, the shape of second closure member **24c** may be modified to form upper and lower loops **45c** and **47c**. As shown in Figure 7b, closure member **22c** may be inverted, and heart-shaped loop **37c** may be included between loops **32c** and **34c** and connecting strands **36c** and **38c**. Looped ends **33c** of lower loop **47c** and looped ends **35c** of heart-shaped loop **37c** serve as vertical centering structures that act together to constrain the vertical movement of clip. The first vertical centering structures (*i.e.* looped ends **35c** of heart-shaped loop **37c**) and second vertical centering structures (*i.e.* looped ends **33c** of lower loop **47c**) are opposed across the overlapping layers of the septum. The movement of clip **18c** is thereby limited in the left atrium to the height ℓ_2 of end loops **33c** and in the right atrium to the height ℓ_1 of end loops **35c**. Of course, other embodiments of the present invention may include the same type of vertical centering structures **33c** or **35c** in one or both closure members **22** and **24**. Another advantage of the configuration of the clip device shown in Figures 7a and 7b is that there is better coverage on both sides of the defect and, as a result, better closure of the defect. Additionally, the configuration provides better dislodgement

resistance since the device, once deployed, has limited movement in the longitudinal direction.

[0049] The connecting members also serve a horizontal centering function. Specifically, the connecting members may be designed to fit within the PFO tunnel such that there is little (or no) horizontal movement once the device is deployed. Horizontal centering is important because the dynamic conditions in the heart may tend to move the device. Of course, various configurations, including bent or slightly bent wires, to position the connecting members within the PFO tunnel are within the scope of this invention.

[0050] In a further embodiment, the movement of clip 18d across the defect is limited by small diameter centering elements 49, which may be of the type disclosed in U.S. Patent No. 5,709,707, hereby incorporated by reference. The centering elements are attached to and connect closure members 22d and 24d. These centering elements may be springs and may be formed of metal, plastic, elastic materials, or shape memory materials (*e.g.* nitinol). The connectors are attached to closure members 22d and 24d such that the inherent tendency of the springs to straighten will center the clip 18d across the defect following its deployment. For example, as shown in Figures 8a and 8b, the springs may be positioned such that they connect point A of closure member 24d with points B and C of closure member 22d. The centering elements may be included in any of the embodiments of clip 18 or any of the embodiments of the invention described herein. The location of the centering elements may be varied according to the application. The centering elements are represented by coils in Figures 8a and 8b.

[0051] While closure members 22 and 24 of the various embodiments of clip 18 have been shown and described in pairs, the present invention is not limited to these illustrated combinations. In fact, a clip device including any of the various embodiments of closure member 22 disclosed herein in combination with any of the various embodiments of closure member 24 disclosed herein may be used to close a PFO and is considered within the scope of the present invention.

[0052] Referring now to Figures 9 and 10, another embodiment of a PFO closure clip according to the present invention, indicated generally at 50, is designed to provide a sufficient gripping force so that the clip maintains its position. The clip 50 includes a first substantially "S"-shaped section 52 and a second substantially "S"-shaped section 54. The first closure member of clip 50 includes a first C-shaped end 68 of the section 52

joined to a first C-shaped end 70 of the section 54 by a looped joinder strand 72 having three substantially "U"-shaped loops 74, 76, and 78. The second closure member of clip 50 includes a second C-shaped end 56 of the section 52 joined to a second C-shaped end 58 of the section 54 by a looped joinder strand 60 having three substantially "U"-shaped loops 62, 64, and 66. Loops 74, 76, and 78 are oriented in an opposed relationship to the loops 62, 64, and 66. It will be noted in Figure 10 that the loops 62 and 66 are overlapped by the loops 74 and 78. Although Figures 9 and 10 depict a clip including a looped joinder strand having three U-shaped loops, the looped joinder strands of the clip devices according to the present invention may include one or more U-shaped loops. The first closure member is connected to the second closure member by connecting members attached to the closure members at their peripheries, *i.e.* ends 56 and 68 are connected by connecting strand 65 of section 52, while ends 58 and 70 are connected by connecting strand 67 of section 54. Connecting strands 65 and 67 are designed to extend through the inclined PFO tunnel 20 between septum primum and septum secundum.

[0053] Figures 11 and 12 show the clip 50 in place to close a PFO. Clip 50 may be elongated and deployed through a catheter. The catheter enters the right atrium and is inserted through the PFO tunnel into the left atrium. The second closure member (*i.e.* ends 56 and 58 and joinder strand 60) is deployed into the left atrium, where it resumes the shape shown in Figure 9. The catheter is then withdrawn through the PFO tunnel into the right atrium such that connecting strands 65 and 67 are deployed and extend through the PFO tunnel. Finally, the first closure member (*i.e.* ends 68 and 70 and joinder strand 72) is deployed into the right atrium, where it resumes the shape shown in Figure 9. When so deployed, the first and second closure members apply a compressive force to the septal tissues, as shown in Figures 11 and 12. As shown in Figure 12, loops 62, 64, and 66 of joinder strand 60 exert a compressive force against the surface of septum primum in the left atrium. Similarly, loops 74, 76, and 78 of joinder strand 72 exert a compressive force against the surface of septum secundum in the right atrium. These opposing forces urge the septal tissues together to close the defect.

[0054] Referring now to Figures 13-17, still another embodiment of the PFO closure clip of the present invention is provided. The clip 80 includes a first closure member having two, spaced prongs, *e.g.* spines, 96 and 98. Spines 96 and 98 are joined at their peripheries to angled sections 90 and 92, which are designed to extend through the PFO tunnel, by a first joinder 94. Angled sections 90 and 92 are connected by second joinders

86 and 88 to the periphery of the second closure member, which includes two spaced, downwardly extending prongs, *e.g.* arms, 82 and 84. While the clip 80 shown in Figure 13 includes two spines in the first closure member, a greater number of spaced spines may be included by increasing the length of the first joiner 94 so as to space angled sections 90 and 92 and arms 82 and 84 further apart. As the number of spines in clip 80 is increased, the number of contact points between the clip device and the septal tissue is increased, thereby increasing the compressive force applied to septum primum and septum secundum and, in at least some embodiments, producing a more effective closure of the defect.

[0055] The clip 80 may be delivered through a catheter in a straight, elongate form. In at least some embodiments, the clip 80 is constructed from a shape memory material (*e.g.* nitinol), such that clip 80 resumes the shape shown in Figure 13 following its deployment. Again, materials having thermal shape memory or superelasticity or both may be used. Thus, as shown in Figure 14, clip 80 may be straightened and delivered through a catheter or sheath 100 with arms 82 and 84 positioned adjacent the forward end of the catheter 100. The catheter 100 is inserted into the left atrium through the PFO tunnel 20 between septum primum and septum secundum, and the second closure member (*i.e.* arms 82 and 84) is ejected up to the joiners 86 and 88. The arms 82 and 84 deploy downwardly into engagement with the surface of septum primum in the left atrium, and the catheter 100 is then drawn back through the PFO tunnel 20, deploying angled sections 90 and 92, which extend through the PFO tunnel. Finally, the first closure member is ejected from the catheter 100, and spines 96 and 98 engage the surface of septum secundum in the right atrium, as shown in Figure 15. The arms 82 and 84 and spines 96 and 98 exert a compressive force upon septum primum and septum secundum, thereby closing the defect.

[0056] The clip 80 may be modified in various ways. Thus, according to some embodiments (Figures 16 and 17), the clip 80 is modified such that it engages a more extensive area of the septal tissue surrounding the PFO, thereby producing a more effective closure of defect. For example, in some embodiments, the clip 80 may be modified such that it engages septal tissue along the length of the defect. In one such embodiment, indicated generally at 102 in Figure 16, the spines 96 and 98 of the first closure member are modified to include laterally extending bars 104 and 106 at their free upper ends. When clip 102 is deployed, bars 104 and 106 engage and apply force to a

surface of septum secundum along the length of the defect in the right atrium. Another such embodiment, indicated generally at 110 in Figure 17, includes a single spine 112 in the first closure member that extends upwardly from the second joinder 94 and terminates in a lateral crossbar 114. Lateral crossbar 114, like bars 104 and 106 of clip 102, engages a surface of septum secundum along the length of the defect in the right atrium.

Additionally, a curved cross strut 116 may be included in the second closure member between arms 82 and 84 of clip 102 or 110. Cross strut 116 engages a surface of septum primum across the length of the defect in the left atrium, thereby increasing the compressive force applied to the defect by clip 102 or 110.

[0057] In still other embodiments, the clip 80 may be modified to encourage the anatomical closure of the overlapping layers of septal tissue by additional means. For example, as shown in Figure 16, a flexible strip 108 formed of a material capable of promoting tissue growth may be attached between inclined sections 90 and 92 of clip 102. Strip 108 will unfurl when the clip is deployed and will be positioned in the PFO tunnel. Strip 108 may be formed of any flexible material capable of promoting tissue growth, including but not limited to polyester fabrics, Teflon-based materials, polyurethanes, other natural materials (*e.g.* collagen), or combinations of the foregoing materials. Although strip 108 is depicted as part of clip 102, it may be included in any of the various embodiments disclosed herein.

[0058] Any of the clip embodiments of the present invention may include a tissue scaffold on one or both closure members. The tissue scaffold promotes encapsulation and endothelialization, thereby further encouraging anatomical closure of septum primum and septum secundum. The tissue scaffold may be formed of any flexible material capable of promoting tissue growth, including but not limited to polyester fabrics, Teflon-based materials, polyurethanes, other natural materials (*e.g.* collagen), or combinations of the foregoing materials.

[0059] The compressive force applied by the closure members of any of the various embodiments described herein may be adjusted in a variety of ways. For example, the thickness of the strand or wire may be increased or decreased to adjust the compressive force. In general (and with other design considerations similar), a thicker strand or wire will provide higher compressive force. Additionally, various closure member configurations may be chosen to increase the compressive force. Generally, bends with smaller angles will provide more compressive force. One skilled in the art will recognize

the various design modifications that could be used to adjust the compressive force of the device.

[0060] Having described embodiments of the present invention, it should be apparent that the invention is capable of other and different embodiments and may be modified in various respects, all without departing from the scope of the invention as defined by the appended claims. Accordingly, the foregoing drawings and description are to be regarded as illustrative in nature and not in a restrictive or limiting sense.

What is claimed is:

1. A device for closing two overlapping layers of septum primum and septum secundum dividing a left atrium and a right atrium in a mammalian heart, comprising first and second opposed closure members disposed on opposite sides of the septum, each closure member having a periphery, and at least two connecting members attached to each of said closure members at a location on the periphery of said closure members, wherein said connecting members extend between the overlapping layers of septum primum and septum secundum such that said first and second closure members cooperate to provide a compressive force to the overlapping layers of septum primum and septum secundum.
2. The device of claim 1, wherein said first closure member is sized and shaped to apply a compressive force to the layers of septum primum and septum secundum in the right atrium and said second closure member is sized and shaped to apply a compressive force to the layers of septum primum and septum secundum in the left atrium.
3. The device of claim 1, wherein said device includes a material selected from the group consisting of metals, nonmetallic materials, bioabsorbable polymers, spring steel, shape memory materials, bioabsorbable shape memory polymers, and combinations thereof.
4. The device of claim 3, wherein said device is constituted at least in part of nitinol.
5. The device of claim 1, wherein at least one of said first and second closure members includes an arcuate peak joining two elongate side strands.

6. The device of claim 5, wherein said first and second closure members of said device both include arcuate peaks, and said arcuate peaks are oriented such that said arcuate peak of said first closure member is directed generally in a first direction and said arcuate peak of said second closure member is directed generally in an opposite direction.
7. The device of claim 6, wherein said side strands are oriented from said arcuate peak such that when implanted, said side strands contact the septum and apply a compressive force against the septum.
8. The device of claim 6, wherein said closure members have a longitudinal axis and wherein said peak and said side strands are configured to extend in the general direction of said longitudinal axis.
9. The device of claim 8, wherein said first closure member further comprising a point adapted to facilitate removal or repositioning of the device.
10. The device of claim 8, wherein said peak and said side strands of at least one of said first and second closure members extend through the vertical center of said at least one closure member, and said peak points downward when the device is deployed *in vivo*.
11. The device of claim 1, wherein the passage between septum primum and septum secundum forms a longitudinal axis and wherein said first and second closure members are configured to prevent movement along said longitudinal axis when said device is deployed.
12. The device of claim 11, wherein said first closure member contains first vertical centering structures and said second closure member contains second vertical

centering structures such that, when said device is deployed, said first vertical centering structures are located in the right atrium, said second vertical centering structures are located in the left atrium, and said first and second vertical centering structures are opposed across the overlapping layers of septum primum and septum secundum.

13. The device of claim 12, wherein said first and second vertical centering structures include loops.
14. The device of claim 1, wherein said device further includes at least one centering element connecting said first and second closure members.
15. The device of claim 14, wherein said at least one centering element includes a material selected from the group consisting of metals, plastics, elastic materials, and shape memory materials.
16. The device of claim 15, wherein said at least one centering element is constituted at least in part of nitinol.
17. The device of claim 1, wherein each of said first and second closure members includes two C-shaped ends connected by a looped joinder strand including at least one U-shaped loop.
18. The device of claim 17, wherein said looped joinder strand of said first closure member is directed generally in a first direction and said looped joinder strand of said second closure member is directed generally in an opposite direction.
19. The device of claim 18, wherein said looped joinder strand includes three U-shaped loops.

20. The device of claim 18, wherein said looped joinder strand of said second closure member applies a compressive force to septum primum in the left atrium and said looped joinder strand of said first closure member applies a compressive force to septum secundum in the right atrium.
21. The device of claim 1, wherein at least one of said first and second closure members includes at least one prong.
22. The device of claim 21, wherein at least one of said first and second closure members includes at least two spaced prongs.
23. The device of claim 21, wherein said at least one prong of said first closure member further includes a lateral bar located at a proximal end of said prong.
24. The device of claim 22, wherein said at least two spaced prongs of said second closure member are connected by a strut oriented perpendicularly to said prongs.
25. The device of claim 21, wherein said at least one prong of said first closure member applies a compressive force to septum secundum in the right atrium and said at least one prong of said second closure member applies a compressive force to septum primum in the left atrium when said device is deployed.
26. The device of claim 1, wherein said at least two spaced central connecting members are connected by a strip of material capable of promoting tissue growth.
27. The device of claim 26, wherein said material is selected from the group consisting of polyesters, Teflon-based materials, polyurethanes, collagen, and combinations thereof.

28. The device of claim 1, wherein at least one of said first and second closure members further includes a tissue scaffold.
29. The device of claim 28, wherein said tissue scaffold includes a material selected from the group consisting of polyesters, Teflon-based materials, polyurethanes, collagen, and combinations thereof.
30. The device of claim 1, further comprising a catheter, wherein said catheter contains said device in an elongated form.
31. A method of closing two overlapping layers of septum primum and septum secundum dividing a left atrium and a right atrium in a mammalian heart, comprising:
- a. inserting a catheter into the right atrium of said heart, said catheter containing a closure device including first and second closure members and at least two spaced central connecting members, wherein each of said closure members has a periphery and each of said central connecting members is attached to each of said closure members at a location on the periphery of said closure members;
 - b. inserting said catheter between the overlapping layers of septum primum and septum secundum and into the left atrium of said heart;
 - c. deploying said second closure member into the left atrium;

- d. retracting said catheter between the overlapping layers of septum primum and septum secundum and into the right atrium, said at least two spaced central connecting members extending at an angle between septum primum and septum secundum;
 - e. further retracting said catheter out of the right atrium, such that said first closure member is deployed into the right atrium and applies a compressive force to said overlapping layers of septum primum and septum secundum in said right atrium, whereby said first and second closure members cooperate to close said overlapping layers of septum primum and septum secundum.
32. The method of claim 31, wherein said closure device is provided in said catheter in an elongated form.
33. The method of claim 31, wherein said device includes a material selected from the group consisting of metals, nonmetallic materials, bioabsorbable polymers, spring steel, shape memory materials, bioabsorbable shape memory polymers, and combinations thereof.
34. The method of claim 33, wherein said device is constituted at least in part of nitinol.
35. The method of claim 31, wherein at least one of said first and second closure members of said device includes an arcuate peak joining two elongate side strands
36. The method of claim 31, wherein said first and second closure members of said device both include arcuate peaks, and said arcuate peaks are oriented such that said arcuate peak of said first closure member is directed generally in a first

direction and said arcuate peaks of said second closure member is directed generally in an opposite direction.

37. The method of claim 36, wherein said side strands are oriented from said arcuate peak such that, when implanted, said side strands contact the septum and apply a compressive force against the septum.
38. The method of claim 36, wherein said closure members have a longitudinal axis and wherein said peak and said side strands are configured to extend in the general direction of said longitudinal axis.
39. The method of claim 38, wherein said first closure member further comprises a point adapted to facilitate removal or repositioning of the device.
40. The method of claim 38, wherein at said peak and said side strands of at least one of said first and second closure members extend through the vertical center of said at least one closure member, and said peak points downward.
41. The method of claim 31, wherein the passage between septum primum and septum secundum forms a longitudinal axis and said first and second closure members are configured to prevent movement along said longitudinal axis.
42. The method of claim 41, wherein said first closure member contains first vertical centering structures and said second closure member contains second vertical centering structures such that said first and second vertical centering structures are opposed across the overlapping layers of septum primum and septum secundum.
43. The method of claim 42, wherein said first and second vertical centering structures include loops.

44. The method of claim 31, wherein said device further includes at least one centering element connecting said first and second closure members.
45. The method of claim 31, wherein each of said first and second closure members includes two C-shaped ends connected by a looped joinder strand including at least one U-shaped loop.
46. The method of claim 45, wherein said looped joinder strand of said first closure member is directed generally in a first direction and said looped joinder strand of said second closure member is directed generally in an opposite direction.
47. The method of claim 46, wherein said looped joinder strand includes three U-shaped loops.
48. The method of claim 31, wherein each of said first and second closure members includes at least one prong.
49. The method of claim 48, wherein each of said first and second closure members includes at least two spaced prongs.
50. The method of claim 48, wherein said at least one prong of said first closure member further includes a lateral bar located at a proximal end of said prong.
51. The method of claim 49, wherein said at least two spaced prongs of said second closure member are connected by a strut oriented perpendicularly to said prongs.
52. The method of claim 31, wherein said at least two spaced central connecting members are connected by a strip of material capable of promoting tissue growth.

53. The method of claim 52, wherein said material is selected from the group consisting of polyesters, Teflon-based materials, polyurethanes, collagen, and combinations thereof.
54. The method of claim 31, wherein at least one of said first and second closure members further includes a tissue scaffold.
55. The method of claim 54, wherein said tissue scaffold includes a material selected from the group consisting of polyesters, Teflon-based materials, polyurethanes, collagen, and combinations thereof.
56. The method of claim 31, further comprising retrieving and removing said closure device after it has been deployed.
57. A device for closing two overlapping layers of septum primum and septum secundum dividing a left atrium and a right atrium in a mammalian heart, comprising at least one closure member disposed on one side of the septum, said at least one closure member having a periphery, and a connecting member attached to said periphery of said closure member, wherein said connecting member extends between the overlapping layers of septum primum and septum secundum such that said closure member cooperates with the connecting member to provide a compressive force to the overlapping layers of septum primum and septum secundum.
58. The device of claim 57, further comprising at least two connecting members attached to said periphery of said closure member.

59. The device of claim 57, wherein said connecting member includes a generally straight section adapted to be disposed between septum primum and septum secundum.
60. The device of claim 59, wherein said connecting member includes a curved section at the end of said connecting member not attached to said closure member.
61. The device of claim 60, wherein said closure member and said connecting member are formed of a single wire.
62. The device of claim 60, wherein said closure member has a configuration designed to distribute forces along the septum.
63. A system for closing two overlapping layers of septum primum and septum secundum dividing a left atrium and a right atrium in a mammalian heart, comprising first and second opposed closure members disposed on opposite sides of the septum, each closure member having a periphery, and at least two connecting members attached to each of said closure members at a location on the periphery of said closure members,
- said system having a first configuration adapted to be delivered through a catheter, said first configuration being of a generally low profile,
- said system having a second configuration once delivered into the desired delivery site, said second configuration including said connecting members adapted to extend between the overlapping layers of septum primum and septum secundum such that said first and second closure members cooperate to provide a compressive force to the overlapping layers of septum primum and septum secundum.

64. The system of claim 63, wherein said system further comprises a catheter through which said closure device is adapted to be delivered when in said first configuration.
65. The system of claim 63, wherein, in said second configuration, said first closure member is sized and shaped to apply a compressive force to the layers of septum primum and septum secundum in the right atrium and said second closure member is sized and shaped to apply a compressive force to the layers of septum primum and septum secundum in the left atrium.
66. The system of claim 63, wherein said device includes a material selected from the group consisting of metals, nonmetallic materials, bioabsorbable polymers, spring steel, shape memory materials, bioabsorbable shape memory polymers, and combinations thereof.
67. The system of claim 66, wherein said device is constituted at least in part of nitinol.
68. The system of claim 63, wherein, in said second configuration, at least one of said first and second closure members of said device includes an arcuate peak joining two elongate side strands.
69. The system of claim 63, wherein, in said second configuration, said first and second closure members of said device both include arcuate peaks, and said arcuate peaks are oriented such that said arcuate peak of said first closure member is directed generally in a first direction and said arcuate peaks of said second closure member is directed generally in an opposite direction.

70. The system of claim 69, wherein, in said second configuration, said side strands are oriented from said arcuate peak such that said side strands contact the septum and apply a compressive force against the septum.
71. The system of claim 69, wherein, in said second configuration, said closure members have a longitudinal axis and wherein said peak and said side strands extend in the general direction of said longitudinal axis.
72. The system of claim 71, wherein said first closure member further comprises a point adapted to facilitate removal or repositioning of the device.
73. The system of claim 71, wherein, in said second configuration, said peak and said side strands of at least one of said first and second closure members extend through the vertical center of said at least one closure member, and said peak points downward.
74. The system of claim 63, wherein the passage between septum primum and septum secundum forms a longitudinal axis and, in said second configuration, said first and second closure members are configured to prevent movement along said longitudinal axis.
75. The system of claim 74, wherein, in said second configuration, said first closure member contains first vertical centering structures and said second closure member contains second vertical centering structures, such that when said device is deployed, said first vertical centering structures are located in the right atrium, said second vertical centering structures are located in the left atrium, and said first and second vertical centering structures are opposed across the overlapping layers of septum primum and septum secundum.

76. The system of claim 75, wherein, in said second configuration, said first and second vertical centering structures include loops.
77. The system of claim 63, wherein said device further includes at least one centering element connecting said first and second closure members.
78. The system of claim 63, wherein, in said second configuration, each of said first and second closure members of said device includes two C-shaped ends connected by a looped joinder strand including at least one U-shaped loop.
79. The system of claim 78, wherein, in said second configuration, said looped joinder strand of said first closure member is directed generally in a first direction and said looped joinder strand of said second closure member is directed generally in an opposite direction.
80. The system of claim 79, wherein, in said second configuration, said looped joinder strand includes three U-shaped loops.
81. The system of claim 63, wherein, in said second configuration, each of said first and second closure members of said device includes at least one prong.
82. The system of claim 81, wherein, in said second configuration, each of said first and second closure members of said device includes at least two spaced prongs.
83. The system of claim 81, wherein, in said second configuration, said at least one prong of said first closure member further includes a lateral bar located at a proximal end of said prong.

84. The system of claim 82, wherein, in said second configuration, said at least two spaced prongs of said second closure member are connected by a strut oriented perpendicularly to said prongs.
85. The system of claim 63, wherein said at least two spaced central connecting members are connected by a strip of material capable of promoting tissue growth.
86. The system of claim 85, wherein said material is selected from the group consisting of polyesters, Teflon-based materials, polyurethanes, collagen, and combinations thereof.
87. The system of claim 63, wherein at least one of said first and second closure members further includes a tissue scaffold.
88. The system of claim 87, wherein said tissue scaffold includes a material selected from the group consisting of polyesters, Teflon-based materials, polyurethanes, collagen, and combinations thereof.
89. A system for closing two overlapping layers of tissue, comprising first and second opposed closure members disposed on opposite sides of the septum, each closure member having a periphery, and
- at least two connecting members attached to each of said closure members at a location on the periphery of said closure members, said connecting members attached to said closure members at an acute angle such that said closure members and said connecting members form a relatively flat device,
- wherein said central connecting members extend between the overlapping layers of tissue such that said first and second closure members cooperate to provide a closure force to the overlapping layers of tissue.

90. The system of claim 89, wherein said system further comprises a catheter through which said closure device is adapted to be delivered in an elongated form.
91. The system of claim 89, wherein said device includes a material selected from the group consisting of metals, nonmetallic materials, bioabsorbable polymers, spring steel, shape memory materials, bioabsorbable shape memory polymers, and combinations thereof.
92. The system of claim 91, wherein said device is constituted at least in part of nitinol.
93. The system of claim 89, wherein at least one of said first and second closure members of said device includes an arcuate peak joining two elongate side strands
94. The system of claim 93, wherein said first and second closure members of said device both include arcuate peaks, and said arcuate peaks are oriented such that said arcuate peak of said first closure member is directed generally in a first direction and said arcuate peak of said second closure member is directed generally in an opposite direction.
95. The system of claim 94, wherein said side strands are oriented from said arcuate peak such that, when implanted, said side strands contact the septum and apply a compressive force against the septum.
96. The system of claim 94, wherein said closure members have a longitudinal axis and wherein said peak and said side strands are configured to extend in the general direction of said longitudinal axis.

97. The system of claim 96, wherein said first closure member further comprises a point adapted to facilitate removal or repositioning of the device.
98. The system of claim 96, wherein said peak and said side strands of at least one of said first and second closure members extend through the vertical center of said at least one closure member, and said peak points downward.

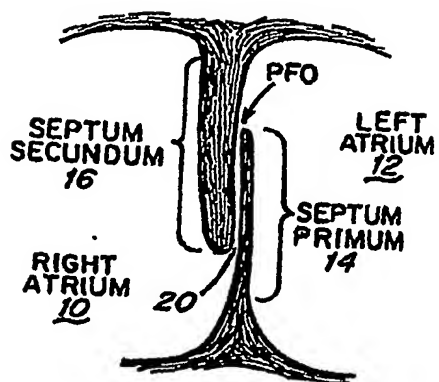


Fig. 1

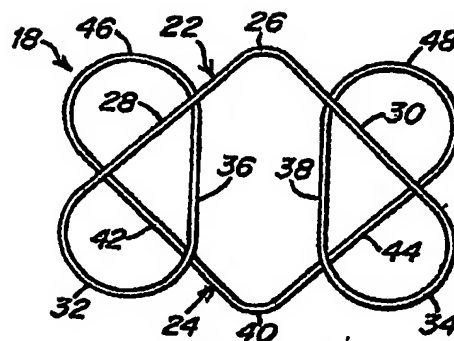


Fig. 2a

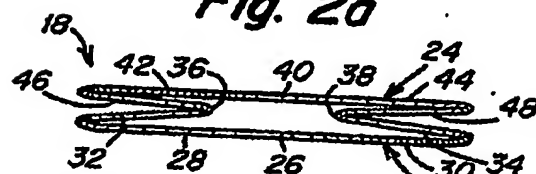


Fig. 2b

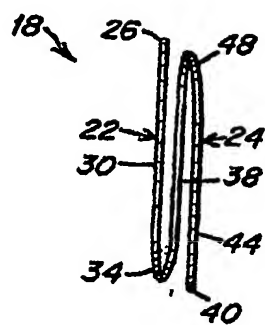


Fig. 3a

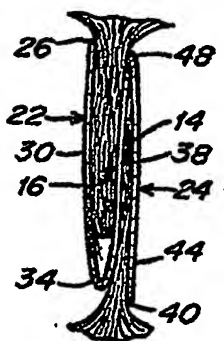


Fig. 3b

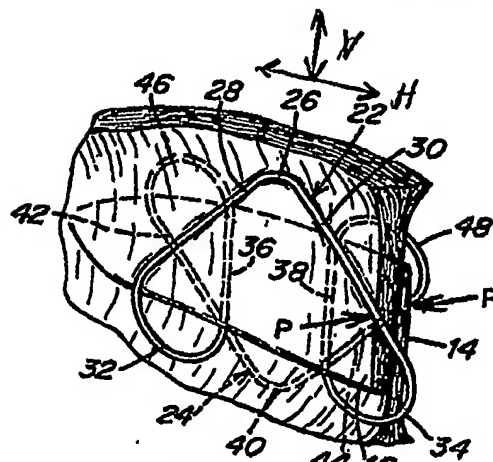


Fig. 4

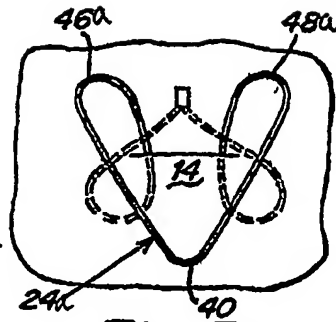


Fig. 5a

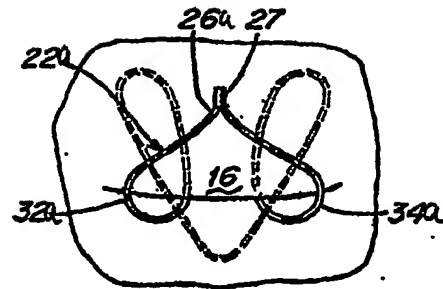


Fig. 5b

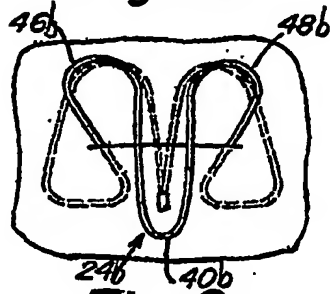


Fig. 6a

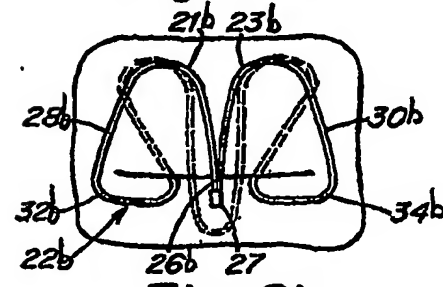


Fig. 6b

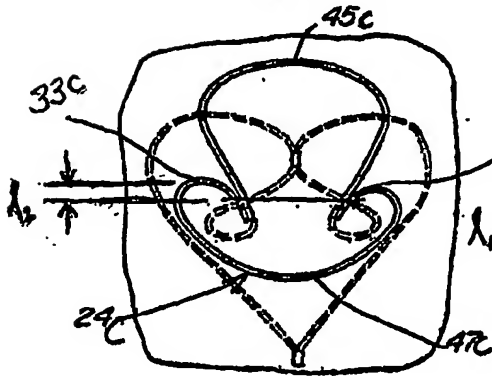


Fig. 7a

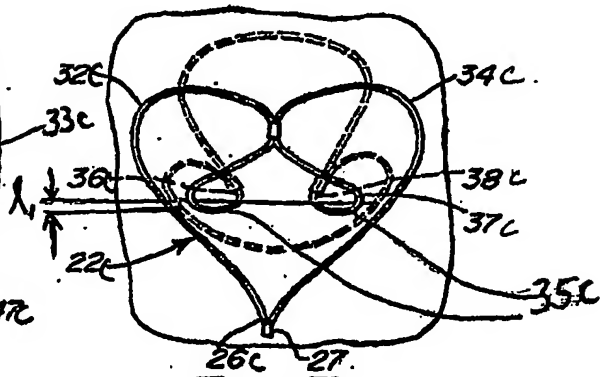


Fig. 7b

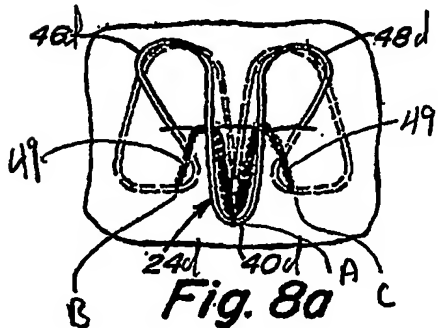


Fig. 8a

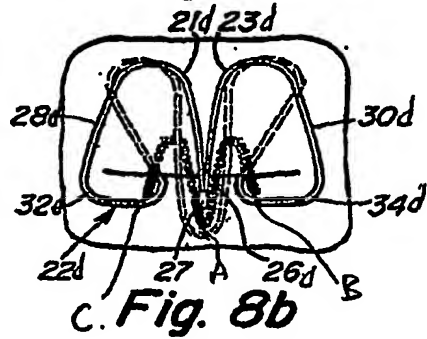


Fig. 8b

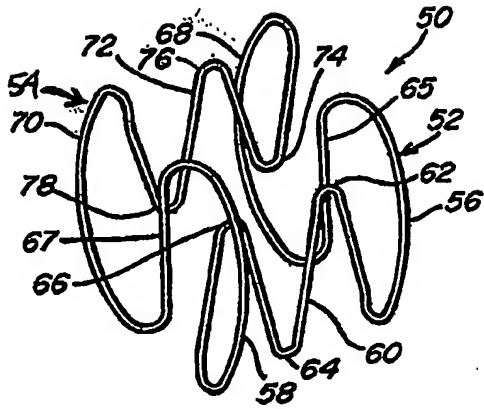


Fig. 9

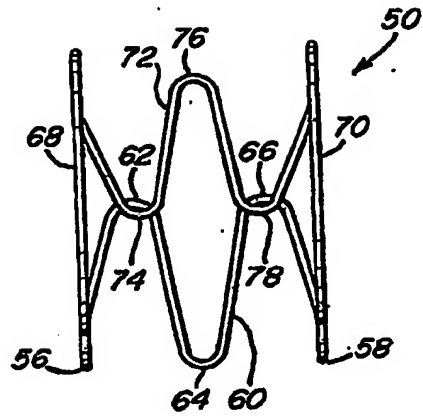


Fig. 10

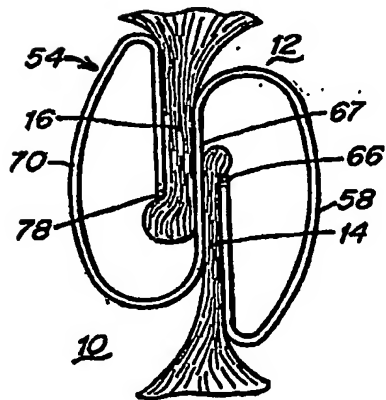


Fig. 11

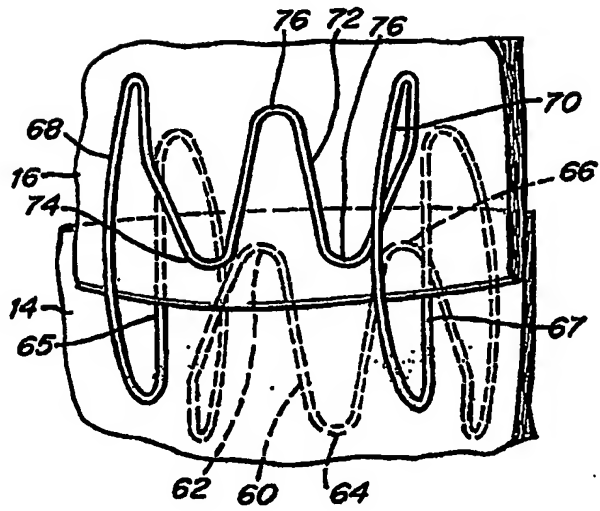


Fig. 12

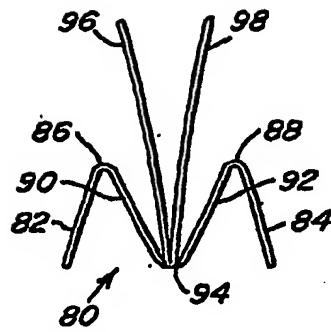


Fig. 13

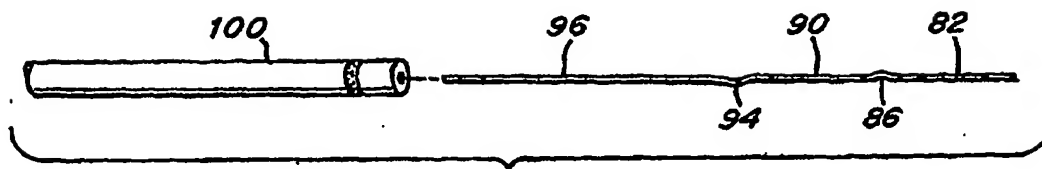


Fig. 14

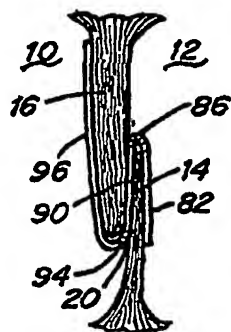


Fig. 15

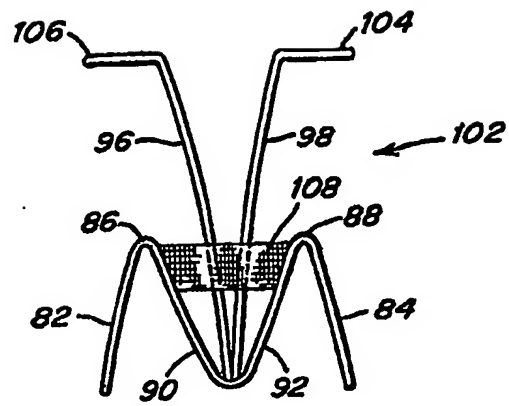


Fig. 16

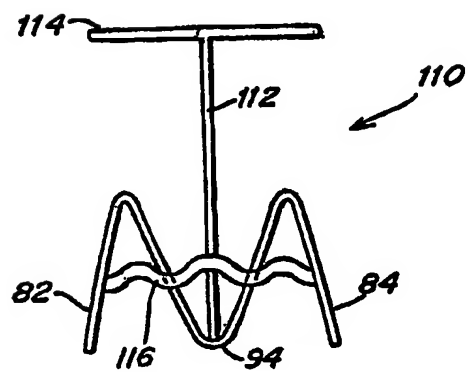


Fig. 17

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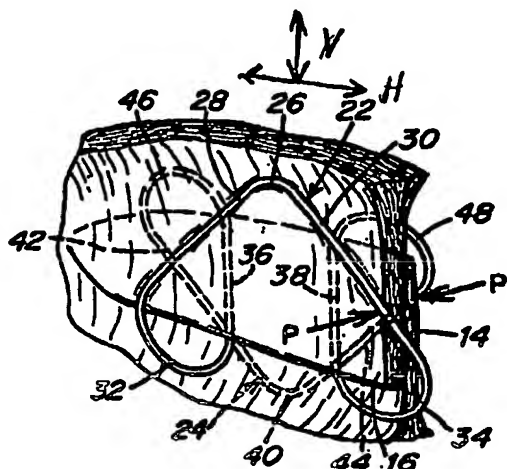
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PATENT FORAMEN OVALE (PFO) CLOSURE CLIPS



(57) Abstract: The clips (18) of the present invention include two closure members (22, 24) joined by at least two spaced central connecting members (36, 38). The clips (18) are designed such that the at least two central connecting members (36, 38) extend through the inclined PFO tunnel and the two closure members (22, 24) compress the overlapping layers of septal tissue, i.e. septum primum and septum secundum, together to close the PFO tunnel. The clips (18) of the present invention take various forms depending, in part upon the distribution of force required to close a given PFO. Thus, embodiments of the closure members (22, 24) include arcuate peaks (26), loops (46, 48), and prongs (96, 98). In yet other embodiments, the closure members (22, 24) include centering elements (49) for centering the device in the desired delivery location and a tissue scaffold (108).

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/09051

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/08

US CL : 606/213

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/151, 213, 216, 217; 24/67.1, 67.3, 67.9

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,425,744 A (FAGAN et al.) 20 June 1995 (20.06.1995), see entire document.	1-3,57-59,63,- 66,77,87-91

☐ Further documents are listed in the continuation of Box C.



See patent family annex.

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"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"O" documents referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

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INTERNATIONAL SEARCH REPORT

PCT/US03/09051

Continuation of B. FIELDS SEARCHED Item 3:

EAST BRS

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